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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
08/474,450	06/07/95	SHUBER	A 0372/0B128

DARBY AND DARBY  
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18M2/0613

EXAMINER

TUNG, J

10

ART UNIT

PAPER NUMBER

1807

DATE MAILED: 06/13/97

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

# Office Action Summary

Application No.  
**08/474,450**

Applicant(s)  
**Shuber, A.P.**

Examiner  
**Joyce Tung**

Group Art Unit  
**1807**



☒ Responsive to communication(s) filed on Feb 10, 1997

☒ This action is **FINAL**.

☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire 3 month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

## Disposition of Claims

☒ Claim(s) 1-18 is/are pending in the application.

Of the above, claim(s) \_\_\_\_\_ is/are withdrawn from consideration.

☐ Claim(s) \_\_\_\_\_ is/are allowed.

☒ Claim(s) 1-18 is/are rejected.

☐ Claim(s) \_\_\_\_\_ is/are objected to.

☐ Claims \_\_\_\_\_ are subject to restriction or election requirement.

## Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on \_\_\_\_\_ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on \_\_\_\_\_ is ☐ approved ☐ disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. § 119

☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some\* ☐ None of the CERTIFIED copies of the priority documents have been  
☐ received.

☐ received in Application No. (Series Code/Serial Number) \_\_\_\_\_

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

\*Certified copies not received: \_\_\_\_\_

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

## Attachment(s)

☐ Notice of References Cited, PTO-892

☒ Information Disclosure Statement(s), PTO-1449, Paper No(s). 7

☐ Interview Summary, PTO-413

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

--- SEE OFFICE ACTION ON THE FOLLOWING PAGES ---

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*Response to Amendment*

1. The objection to the declaration in the Office action mailed October 9, 1996 is withdrawn in light of the amendments of the response filed 2/10/97.
2. The objection to disclosure in paragraph 1 of the Office action mailed October 9, 1996 is withdrawn in light of the amendments of the response filed 2/10/97.
3. The objection to claims 2, 5-7 and 10 in paragraph 2 of the Office action mailed October 9, 1996 is withdrawn in light of the amendments of the response filed 2/10/97.
4. The 35 U.S.C. 112, second paragraph rejection over claims 4 and 12 in paragraph 3 of the Office action mailed October 9, 1996 is withdrawn in light of the amendments of the response filed 2/10/97.
5. The 35 U.S.C 103 rejection over claims 1-12 made in paragraph 4-6 of the Office action mailed October 9, 1996 is MAINTAINED. This rejection is now applied over new claims 13-18.

The arguments of the response filed 2/10/97 have been fully considered, but are not found persuasive.

First, the arguments of the response are directed to methods limitation because the response argues about simultaneous use of a primers under one set of conditions. It is submitted that these arguments are not applicable to product claims, for which "intended use" limitations are not given weight.

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Second, the response argues that the invention uses one set of cycling times and temperature despite different annealing temperatures, and Weighardt et al. do not teach that the primers can be pooled together and used under a single set of cycling times and temperatures in a multiplex polymerase chain reaction, and further that Picci et al. teach away from the invention in that individual primer pairs are added to a reaction sequentially.

Weighardt et al. do suggest that the method can attain the same results in one step using a single set of primers (see pg. 79).

Even though Picci et al. do teach that the method requires individual primer pairs added to a single reaction sequentially, the method of Weighardt et al. use a primer which is the same as the primer of the invention and Weighardt et al. do suggest that the method can have the same results using one step.

Third, the response argues that Weighardt et al. neither teach nor disclose any sequence that provides a high stringency binding site. Nor does Weighardt et al teach or suggest compositions or characteristics that provide such site(s).

In response to this, it is printed out that Weighardt et al. does recite "the entire primers in turn become new and unique high stringency recognition sites in the following PCR cycles" (see pg. 77). The PCR procedure with the tailed primer improved the specificity of the reaction. The benefit of using Weighardt et al.'s primers having non-complementary 5'-end tails would have been expected in the multiplex PCR method of Picci et al.

6. NEW GROUND OF REJECTIONS NECESSITATED BY THE AMENDMENT

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7. The amendment filed 2/10/97 is objected to under 35 U.S.C. 132 because it introduces new matter into the disclosure. 35 U.S.C. 132 states that no amendment shall introduce new matter into the disclosure of the invention. The added material which is not supported by the original disclosure is as follows: "a plurality of amplified target sequences of interest". Support for this cannot be found in the specification..

Applicant is required to cancel the new matter in the response to this Office action.

8. Claims 17 and 18 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. A plurality of amplified target sequences of interest was not disclosed in the specification.

***Claim Rejections - 35 USC § 112***

9. Claims 17 and 18 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

These claims are confusing because of the language "a plurality of amplified target sequences of interest". It cannot be determined from the specification what is encompassed by a plurality of nucleic acids defined only by how said nucleic acids are detected.

10. No claims are allowable over the prior art.

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11. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for response to this final action is set to expire THREE MONTHS from the date of this action. In the event a first response is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event will the statutory period for response expire later than SIX MONTHS from the date of this final action.

12. Any inquiries concerning this communication or earlier communications from the examiner should be directed to Joyce Tung whose telephone number is (703) 305-7112. The examiner can normally be reached on Monday-Friday from 8:30 AM-5:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, W. Gary Jones, can be reached at (703) 308-1152. The fax number for Art Unit 1807 is (703)305-7401.

Any inquiries of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0196.

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13. Papers related to this application may be submitted to Group 1800 by facsimile transmission. Papers should be faxed to Group 1800 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989).

Joyce Tung

June 3, 1997

  
W. GARY JONES  
SUPERVISORY PATENT EXAMINER  
GROUP 1800

6/9/97